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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs and Counterclaim-Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants and Counterclaim-Plaintiffs.	:	Civil Action No. 3:10-CV-01723-JAP-TJB **MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE EXPERT TESTIMONY BY JAMES MORRISON** **CONTAINS HIGHLY CONFIDENTIAL MATERIAL – FILE UNDER SEAL**

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The Takeda Plaintiffs ("Takeda") submit this memorandum in support of their motion *in limine*, pursuant to Federal Rules of Evidence 702 to preclude James Morrison's testimony at trial in relation to opinions rendered in his rebuttal expert report ("Morrison's report"),[1] his October 12, 2012 declaration (D.I. 250) and his October 19, 2012 declaration (D.I. 260) submitted on behalf of Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Zydus").

PRELIMINARY STATEMENT

[redacted] Takeda and Zydus exchanged expert reports regarding the issue of infringement. Both parties had qualified experts opine on whether Zydus' ANDA product described in ANDA 200-816 infringes U.S. Patent Nos. 6,328,994 ("the '994 patent"), 7,431,942 ("the '942 patent"), 7,875,292 ("the '292 patent") (collectively, the "Takeda patents").[2] Although Zydus had its qualified expert, Dr. Brittain, opine on whether its ANDA product infringes the Takeda patents, Zydus also submitted a rebuttal expert report by James Morrison – an FDA expert. There are a number of problems with Morrison's report that warrant preclusion of any testimony by him at trial.

For one, Morrison glaringly lacks the qualifications of one skilled in the relevant art, but nevertheless opines on issues of infringement and invalidity of the Takeda patents. Morrison earned a bachelor's degree in chemistry in 1965 and has no further formal education in that field. He also went to law school for two years, but never finished and never received a law degree. ***Ex. 1***, Morrison Dep. Tr. at 7:1-18. He spent nearly his entire career at FDA. ***Ex. 2***, Morrison CV. Indeed, he describes himself in his report as an "expert in the area of FDA procedures and

[1] "References to exhibits herein refer to exhibits attached to the Declaration of Arlene L. Chow."
[2] Plaintiffs also assert that Zydus' ANDA product infringes USP 5,464,632 ("the '632 patent"), but infringement of the '632 patent [redacted]

policy concerning drug regulatory issues and pharmaceutical manufacturers' compliance with FDA regulations and guidelines." ***Ex. 3***, Morrison Rep. at ¶15.

Moreover, Morrison admits that he does not meet the definition of "one skilled in the art" proffered by Zydus and further admits that a FDA expert does not equal "one skilled in the art." Morrison's lack of relevant qualifications renders his opinions nothing more than the speculation of a lay witness. Lastly, a number of Morrison's opinions relating to [redacted] are utterly irrelevant to the issues in this case, which concern only issues of patent infringement and validity. Thus, Morrison's testimony at trial would accomplish only one thing – waste the Court's time and resources.

For the reasons set forth below, Takeda respectfully requests the Court preclude Morrison from testifying at trial as his testimony fails to meet the legal standard of admissibility.

BACKGROUND

This is a patent infringement action under the Hatch-Waxman Act on four patents covering Takeda's Orally Disintegrating Tablet ("ODT") formulation of the blockbuster anti-ulcer drug Prevacid® SoluTab™. Takeda asserts that the drug product described in Zydus' ANDA 200-816 infringes the Takeda patents and USP 5,464,632 ("the '632 patent").

As the Court knows, [redacted]

[3] *See* Briefing in relation to Takeda's Motion for Spoliation Sanctions (D.I. 146, 156, 160, 164), Zydus' Motion for Leave to Amend its Invalidity and Noninfringement Contentions (D.I. 179, 181, 184), and Zydus' Motion for Reconsideration of the Court's Order Denying Zydus' Motion for Leave to Amend (D.I. 196).

[redacted][4] *See* ***Ex. 4***, [redacted] [redacted] D.I. 236 at 13-16. [redacted] [redacted] D.I. 265 at 1-2.

[redacted], fully qualified experts for both Takeda (Dr. Bugay) and Zydus (Dr. Brittain) opined on the issue of infringement. However, in addition to serving Dr. Brittain's expert report to rebut Dr. Bugay's infringement testing, Zydus submitted Morrison's report purporting to do the same. The problem is that his opinions have no legal or factual basis. For example, Morrison improperly opines on [redacted]. Morrison also improperly opines on infringement and invalidity issues regarding the Takeda patents, but touts himself as a FDA expert and not one skilled in the art of the Takeda patents. *See id.* at ¶¶27, 32-34. Needless to say, Morrison's testimony should be precluded.

[4] [redacted].

ARGUMENT

I. Legal Standard

"Under the Federal Rules of Evidence [702], a trial judge acts as a 'gate keeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable.'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589-92 (1993))); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (extending *Daubert's* framework to all expert testimony). In determining the admissibility of expert testimony under *Daubert*, courts must weigh three factors: (1) the expert's qualifications; (2) the reliability of the expert's analysis; and (3) the "fit" of the expert's testimony to the facts and issues in the case. *See In re Paoli R. R. Yard PCB Litig.*, 35 F.3d 717, 742-43 (3d Cir. 1994). Although this third factor is essentially a relevance requirement, "the standard is higher than bare relevance."[5] *See Daubert*, 509 U.S. at 591; *Paoli*, 35 F.3d at 745 n.13. In short, Morrison's testimony fails to meet all three factors.

II. Factor 1: Morrison Lacks the Qualifications of One Skilled in the Art

Morrison improperly opines on infringement and invalidity, while lacking the necessary qualifications of one skilled in the relevant art. *See Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008) (holding it improper to "permit a witness to testify as an expert on the issues of noninfringement or invalidity unless that witness is qualified as an expert in the pertinent art"). In his report, Morrison opines on [redacted]

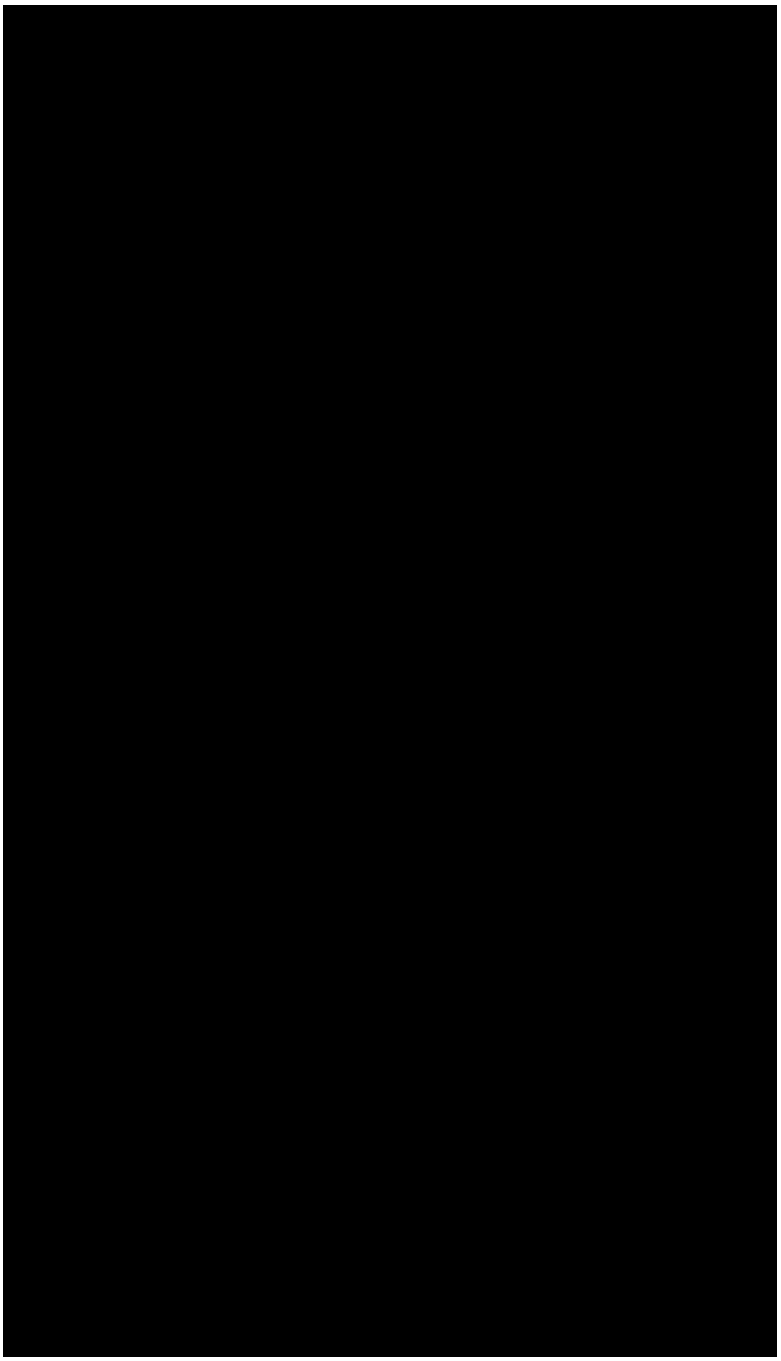
[5] Under Fed. R. Evid. 401, evidence is relevant if "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action."

[redacted]. Yet, Morrison puts the cart before the horse. Morrison touts himself only as a FDA expert and nothing more, presumably because he knew he lacked the necessary qualifications to be "one skilled in the art."

In fact, Morrison admits that he does not meet any portion of Zydus' own definition of "one skilled in the art." Dr. Meyer-Stout, Zydus' claim construction expert, defined "one skilled in the art" for the purposes of this case as having "a high level of education (such as a Ph.D. in Pharmaceutical Chemistry or Pharmaceutics), and several years of training or experience devoted to the study of drug formulation and manufacturing, dosage form disintegration, dosage form disintegration, multiparticulate systems and particle size analysis." ***Ex. 5***, Meyer-Stout C.C. Decl. at ¶11. During his deposition, Morrison [redacted]:

[redacted]

[6] Morrison further admitted he has no relevant experience in patent infringement cases. Indeed, the only case where Morrison provided expert testimony regarding the construction of a patent involved patent claims that correlated with FDA requirements. ***Ex. 1***, Morrison Dep. Tr. at 30:2-17.



See ***Ex. 1***, Morrison Dep. Tr. at 7:23-9:14, 31:10-15 (emphasis added).

Moreover, an FDA expert is not an expert in the art of the Takeda patents. FDA, itself, repeatedly asserts its lack of expertise in assessing pharmaceutical patents. *See, e.g.*, *Andrx Pharms. Inc. v. Biovail Corp.*, 276 F.3d 1368, 1378 (Fed. Cir. 2002) (noting FDA's assertion that "FDA does not have the expertise to review patent information") (citation omitted); *Dr. Reddy's*

Labs., Inc. v. Thompson, 302 F. Supp. 2d 340, 362 (D.N.J. 2003) (recognizing FDA's lack of expertise in patents). Morrison also recognizes FDA's lack of expertise in patents. ***Ex. 1***, Morrison Dep. Tr. at 50:2-4 ("Q. It's true, isn't it, the FDA is not [an] expert in patent matters and in fact doesn't hold itself out to be [an] expert in patent matters? A. That's correct.").

Because Morrison clearly lacks the necessary qualifications to be one skilled in the relevant art, the Court should exclude Morrison from improperly opining on infringement and invalidity of the Takeda patents.

III. Factor 2: Morrison's Testimony is Not Reliable

As Morrison does not possess the necessary qualifications of one skilled in the art, it follows that his opinions on patent-related matters are not reliable. The Court of Appeals for the Third Circuit recognizes that the expert's level of expertise affects the reliability of his testimony such that where an expert's qualifications are sufficiently low, the testimony may be excluded under the reliability prong. *See Paoli*, 35 F.3d 741; *Elcock v. Kmart Corp.*, 233 F.3d 734, 749 (3d Cir. 2000).

Despite his lack of expertise, Morrison makes a number of baseless opinions. For example, Morrison speculates [redacted] ***Ex. 3***, Morrison Rep. at ¶32. However, Morrison provides no explanation as to his basis for forming such an opinion. Morrison similarly provides no basis for his opinion [redacted]

[redacted][7] *See id.* at ¶28.

Based on Morrison's lack of qualifications and the absence of a basis for his opinions, the Court should exclude his testimony as unreliable.

IV. Factor 3: Morrison's Testimony Does Not "Fit" the Facts and Issues of the Case

Morrison also improperly opines on irrelevant FDA matters. For example, Morrison opines [redacted]:

- [redacted] and
- [redacted]

Ex. 3, Morrison Rep. at ¶¶22-23. Moreover, Morrison opines [redacted]:

- [redacted];
- [redacted];
- [redacted]; and
- [redacted].

Ex. 3, Morrison Rep. at ¶¶28-29, 31, 33. But whatever FDA believes or might conclude is wholly irrelevant to whether Zydus' ANDA product infringes the Takeda patents. Indeed, Morrison recognizes that [redacted]

[7] [redacted].

[redacted]:

[redacted]

Ex. 1, Morrison Dep. Tr. at 50:22-51:7 (emphasis added). In light of this candid admission and the relevant case law, his personal views undoubtedly would not help the Court "understand the evidence [or] determine a fact in issue." Fed. R. Evid. 702.

First and foremost, [redacted] has absolutely no bearing in this case. Courts consistently recognize that FDA standards are separate and distinct from patent standards and thus, have no relevance in patent cases.[8] *See, e.g.*, *Scott v. Finney*, 34 F.3d 1058, 1063-64 (Fed. Cir. 1994) (holding Title 35 does not require the "high standards" of FDA testing); *Hoffman-La Roche Inc. v. Apotex Inc.*, Civ. No. 07-4417, 2012 WL 1637736, at *9 n.9 (D.N.J. May 7, 2012) (finding FDA requirements "are not relevant" as the "patent does not claim compliance with FDA requirements"). Morrison also recognizes this distinction. ***Ex. 1***, Morrison Dep. Tr. at 51:3-7 ("A. What the patent says is not within FDA's purview").

Second, [redacted]. ***Ex. 6***, Gurram 30(b)(6) Dep. Tr. at

[8] The patent cases where FDA standards were considered by the court are not applicable here. The Takeda patents do not claim a method of treatment or a "pharmaceutically effective" composition and no parties have asserted that FDA standards were relevant in interpreting the scope of the patents. *See, e.g.*, *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 718 (Fed. Cir.1998) (considering FDA requirements in construing claim limitations that relate to treatment with pharmaceuticals); *Warner-Lambert Co. v. Teva Pharms. USA*, Civ. No. 99-922, 2002 WL 33829991, at *7-8 (D.N.J. June 13, 2002) (finding patentee contended claim term should be defined as meeting FDA requirements).

32:19-36:12 ("[d]efinitely it is not by the request of agency"). Moreover, Morrison stated [redacted]. ***Ex. 1***, Morrison Dep. Tr. at 49:5-10. Accordingly, [redacted].

Lastly, Morrison opines on a number of phantom issues. For example, Morrison discusses [redacted]. ***Ex. 3***, Morrison Rep. at ¶¶18-20, 24-26, 30 [redacted] are simply not at issue in this case. The parties only dispute [redacted], a topic on which Morrison is clearly not competent to opine. Thus, in order to prevent a waste of the Court's time and resources, Morrison's irrelevant testimony should be precluded.

CONCLUSION

For the reasons set for above, Takeda respectfully requests that the Court preclude Morrison's testimony at trial.

Respectfully submitted,

Dated: February 28, 2013

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